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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,580	09/30/2003	Hassan Serhan	3518.1010-000 (DEP5077)	9958
21125 7590 04/04/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
SWIGER III, JAMES L				
ART UNIT		PAPER NUMBER		
3733				
NOTIFICATION DATE		DELIVERY MODE		
04/04/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/675,580

Applicant(s)

SERHAN ET AL.

Examiner

JAMES L. SWIGER

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-13, 15, 24 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-13, 15, 24 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/26/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiley et al. (US Patent 6,066,154). Reiley et al. discloses an intervertebral device having a body (21) with a proximal and distal (towards the expandable balloon) portion along a major axis of the body. The body has a conduit extending throughout (disclosed as a catheter in the reference). Reiley et al. also disclose a selectively expandable balloon at the distal end that is configured to distract vertebrae. It is noted that this is considered a functional limitation. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Reiley et al. '154 which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218

USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). It is further noted that the reference teaches various materials which may be polymers (Col. 3, lines 55 through Col. 4, lines 1-35).

Claims 1, 15 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al. (US Patent 6,695,760). Winkler et al. disclose an intervertebral device comprising a body (12) that has a conduit throughout (18). Winkler et al. further disclose a support at the distal portion that is configured to support vertebrae (Fig. 2). The support is configured to support vertebrae in a distracted position. The body is *configured* to selectively engage the support (see distal end of body contacts part of the cage portion, Fig. 1). The support has a height distinct from a width taken along a cross-section of the body perpendicular to a major axis. See separate height and width in Fig. 2. The support is also considered a cage and is further capable of maintaining a natural angle between the distracted vertebrae. Detaching the body portion (as in Fig. 1) to leave Fig.2 in place, would result in the vertebrae still being supported. It is noted that Winkler et al. '760 also discloses a support that is a balloon (46), which also is able to distract vertebrae. It is able to support the vertebrae when filled with fluid delivered through the conduit of the body (Col. 5, lines 1-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al. in view of Zdeblick et al. (US Patent 6,375,655). Winkler et al. disclose the claimed invention except for more specifically wherein a distal portion of the *body* has a height distinct from the width taken along the cross section of the body that is able to distract vertebrae by rotation. Zdeblick et al. disclose a body that compliments the shape of the support apparatus and has a height distinct from a width taken along a cross section of the body perpendicular to the axis. See Fig. 9. See also Col. 9, lines 40-60) for discussion of the shape, and complimenting flat surface for insertion and distraction of an implant support device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Winkler et al. having at least a distal portion of the body having a height distinct from the width taken along the cross section of the body in view of Zdeblick et al. to better arrange the support apparatus and distract the vertebrae.

Claims 12-13 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al. '760 in view of Zdeblick et al. '655. Winkler and Zdeblick et al. disclose the claimed invention except for specific materials used for construction of the support. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its

suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Winkler et al. '760 and Zdeblick et al. and in further view of Marchosky (US Patent 6,413,278). Winkler et al. and Zdeblick et al. disclose the claimed invention including the support and body and also the distinct width and height and body cross section except for having a flowable material (to be used to support the vertebrae, or used with the support). Winkler discloses that a balloon or support may be inflated with a fluid. It is well known in the art to use a biocompatible matrix, or bone-based matrix to facilitate the strengthening of bone. Additionally, Marchosky discloses a fluid with a plurality of bone particles that may be used between vertebrae to help strengthen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zdeblick et al. and Winkler et al. having at least the flowable material in view of Marchoseky to better support and secure the affected spinal area.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 11-13, 15, 24, and 37-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

